DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration
Cincinnati District
6751 Steger Dr.
Cincinnati, OH 45237

April 18, 2003

VIA FEDERAL EXPRESS

Charles A. Smith
Vice President of Operations
Cardinal Medical Specialties, Inc.
4708 Pinewood Rd.
Louisville, KY 40218-2932

WARNING LETTER – CIN-03-16920

Dear Mr. Smith:

An inspection of your medical device manufacturing firm located in Louisville, KY was conducted by our investigators on March 3 & 5, 2003. The inspection revealed that your portable anesthesia devices are adulterated within the meaning of Section 501(h) of the Federal Food, Drug, and Cosmetic Act (the Act), in that the methods used in, or the facilities or controls used for manufacturing, packing, storage, or installation are not in conformance with the Quality System Regulation, Title 21, Code of Federal Regulations (CFR), Part 820.

The deviations are as follows:

1. Failure to establish and maintain procedures for finished device acceptance. **[21 CFR 820.80(d)]**

2. Failure to document finished device acceptance activities. **[21 CFR 820.80(e)]**

3. Failure to establish and maintain procedures to control the design of the device in order to ensure that specified design requirements are met. **[21 CFR 820.30]**

4. Failure to establish and maintain a design history file for each type of device. **[21 CFR 820.30(j)]**

5. Failure to maintain a device master record. **[21 CFR 820.181]**

6. Failure to maintain device history records and to have procedures to ensure that device history records are maintained to demonstrate that the device is manufactured in accordance with the device master record. **[21 CFR 820.184]**

7. Failure to establish and maintain procedures for implementing corrective and preventive action. **[21 CFR 820.100]**

8. Failure to establish and maintain procedures for receiving, reviewing and evaluating complaints. **[21 CFR 820.198]**

9. Failure to establish and maintain procedures to control product that does not conform to specified requirements. **[21 CFR 820.90]**

In addition, the inspection revealed that you are not in compliance with the Medical Device Reporting (MDR) Regulation, 21 CFR Part 803, in that your firm has failed to develop, maintain and implement written Medical Device Reporting Procedures. **[21 CFR 803.17]**

This letter is not intended to be an all-inclusive list of deficiencies at your firm. It is your responsibility to ensure adherence to each requirement of the Act and regulations. The specific violations noted in this letter and in the Form FDA-483 issued at the conclusion of the inspection may be symptomatic of serious underlying problems in your establishment's quality system. You are responsible for investigating and determining the causes of the violations identified by FDA. You also must promptly initiate permanent corrective and preventative action on your quality system.

Federal agencies are advised of the issuance of all Warning Letters regarding medical devices so that this information may be taken into account when awarding contracts. Additionally, no premarket submissions for Class III devices to which the Quality System/Good Manufacturing Practice deficiencies are reasonably related will be cleared or approved until the deficiencies have been corrected. Also, requests for export certificates to foreign governments will be refused until the violations related to the subject devices have been corrected.

You should take prompt action to correct these violations and to establish procedures whereby such violations do not recur. Failure to do so may result in regulatory action without further notice. These actions include, but are not limited to, seizure, injunction and/or civil penalties.

We acknowledge your firm's written response to the FDA-483, received March 31, 2003. However, your response does not provide sufficient detail and documentation for us to evaluate whether your corrective actions are adequate.

Please notify this office in writing within fifteen (15) working days from the date you receive this letter of the specific steps you have taken to correct the violations. For corrections that you cannot complete within fifteen (15) working days, state the reason for the delay and your timeframe for completion. We also ask that you provide documentation of the corrections as they are made and that you explain your plan for preventing these violations in the future.

Please send your reply to the Food and Drug Administration, Attention: Karen Gale Sego, Compliance Officer, 6751 Steger Dr., Cincinnati, OH 45237

Sincerely,

Mary L. Womack for
Carol A. Heppe
Director, Cincinnati District